

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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| Applicant's or agent's file reference P97-39-PCT | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| International application No. PCT/IE 97/00030 | International filing date (day/month/year) 22/04/1997 | (Earliest) Priority Date (day/month/year) 23/04/1996 |
| Applicant KINERTON LIMITED et al. | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ Transcribed by this Authority
4. With regard to the title, ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract, ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 Figure No. _____ ☐ as suggested by the applicant. ☐ None of the figures.
☐ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 97/00030

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K9/16 A61K47/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|---|
| X,Y | WO 93 17668 A (ALKERMES CONTROLLED THERAPEUTI) 16 September 1993 see the whole document | 1-20, 22-25, 27,29-39 |
| X,Y | WO 94 15587 A (KINERTON LIMITED ;SHALABY SHALABY W (US); JACKSON STEVEN A (US); M) 21 July 1994 cited in the application | 1,2, 4-10, 12-20, 22-25, 27,29, 30, 33-35, 38,39 |
| Y | see the whole document --- | 3,11,31, 32,36,37 |
| | -/-- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

1 October 1997

Date of mailing of the international search report

16. 10. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Fischer, W

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 97/00030

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------------|
| Y | EP 0 556 917 A (AKZO NV) 25 August 1993 see the whole document --- | 1-20, 22-25, 27,29-39 |
| A | US 4 767 628 A (HUTCHINSON FRANCIS G) 30 August 1988 cited in the application --- | |
| A | US 3 773 919 A (BOSWELL G ET AL) 20 November 1973 cited in the application ----- | |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 97/00030

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| WO 9317668 A | 16-09-93 | AT 154240 T | 15-06-97 |
| | | AU 668384 B | 02-05-96 |
| | | DE 69311538 D | 17-07-97 |
| | | EP 0630234 A | 28-12-94 |
| | | JP 7507768 T | 31-08-95 |
| | | US 5656297 A | 12-08-97 |
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| WO 9415587 A | 21-07-94 | AU 680650 B | 07-08-97 |
| | | AU 5992194 A | 15-08-94 |
| | | CA 2150574 A | 21-07-94 |
| | | CZ 9501734 A | 17-01-96 |
| | | EP 0678018 A | 25-10-95 |
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| | | NZ 245914 A | 24-02-95 |
| | | US 5389379 A | 14-02-95 |
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| | | AU 6498886 A | 19-02-87 |
| | | AU 560829 B | 16-04-87 |
| | | AU 7998682 A | 26-08-82 |
| | | CA 1169090 A | 12-06-84 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 97/00030

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| US 4767628 A | | DK 45592 A | 03-04-92 |
| | | DK 59182 A | 17-08-82 |
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| | | HK 107890 A | 28-12-90 |
| | | JP 1057098 B | 04-12-89 |
| | | JP 2071701 C | 25-07-96 |
| | | JP 57150609 A | 17-09-82 |
| | | JP 5221871 A | 31-08-93 |
| | | JP 6086390 B | 02-11-94 |
| | | JP 2041069 C | 09-04-96 |
| | | JP 5271051 A | 19-10-93 |
| | | JP 7074143 B | 09-08-95 |
| | | JP 1744093 C | 25-03-93 |
| | | JP 3001330 B | 10-01-91 |
| | | JP 62064824 A | 23-03-87 |
| | | US 5366734 A | 22-11-94 |
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| | | GB 1325209 A | 01-08-73 |
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PATENT COOPERATION TREATY



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P97-39-PCT | FOR FURTHER ACTION | | See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416) |
| International application No. PCT/IE97/00030 | International filing date (day/month/year) 22/04/1997 | Priority date (day/month/year) 23/04/1996 | |
| International Patent Classification (IPC) or national classification and IPC A61K9/16 | | | |
| Applicant KINERTON LIMITED et al. | | | |

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|---|
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

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|---|---|
| Date of submission of the demand 10/11/1997 | Date of completion of this report 30. 07. 98 |
| Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0. Tx: 523656 epmu d Fax: (+49-89) 2399-4465 | Authorized officer Merkl, B Telephone No. (+49-89) 2399-2138  |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE97/00030

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-16 as originally filed

Claims, No.:

1-39 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|------|--------|------|
| Novelty (N) | Yes: | Claims | 1-39 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-39 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-39 |
| | No: | Claims | |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IE97/00030

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IE97/00030

Section V:

1. Reference is made to the following documents:

D1: WO-A-9317668
D2: WO-A-9415587
D3: US-A-4767628
D4: US-A-3773919
D5: EP-A-0556917

2. The methods as defined in present claims 1, 22 and 29 are regarded to be new (Art. 33(2) PCT) with respect to the documents cited in the international search report.

In D1, D3-D5 no ionic conjugate containing a free carboxyl group-containing polymer and a free amino group containing drug is disclosed. D2 discloses said ionic conjugate, but not the claimed methods of making microparticles thereof.

3. The problem of the present application was to provide a method for preparing microparticles of a sustained release ionic conjugate wherein the particles have a similar size and shape. It appears that the methods defined in present claims 1, 22 and 29 refer to a precipitation method and a evaporation method which as such are known methods in the art for the preparation of microparticles (e.g. D1 pages 6 and 7). However, as the ionic conjugate of the present application represents a combination of two compounds which are not chemically bound, the skilled person would not have expected that it behaves in the same manner as the polymers/drugs disclosed in D1, D3-D5. Therefore the skilled person had no hint to use the processes disclosed in D1, D3-D5 in order solve the posed problem.

Section VII:

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1. is not mentioned in the description, nor is this document identified therein.

Claims 38 and 39 contain a reference to the description and are therefore not admissible in each country..

PATENT COOPERATION TREATY

PCT

COMMUNICATION OF
INTERNATIONAL APPLICATIONS

(PCT Article 20)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

Date of mailing:

27 November 1997 (27.11.97)

in its capacity as designated Office

The International Bureau transmits herewith copies of the international applications having the following international application numbers and international publication numbers:

International application no.:

PCT/IE97/00030

International publication no.:

WO97/39738

**CORRECTED VERSION
VERSION CORRIGEE**The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14 35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|--|--|
| Date of mailing (day/month/year) 27 November 1997 (27.11.97) | |
| International application No. PCT/IE97/00030 | Applicant's or agent's file reference P97-39-PCT |
| International filing date (day/month/year) 22 April 1997 (22.04.97) | Priority date (day/month/year) 23 April 1996 (23.04.96) |
| Applicant IGNATIOUS, Francis et al | |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
10 November 1997 (10.11.97)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Marie-José Devillard |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |